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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/614,790 | 07/12/2000 | Sharon F. Kleyne | HME/7982.001 | 2570 |

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| EXAMINER | |
|---|---|
| WILLIS, MICHAEL A | |
| ART UNIT | PAPER NUMBER |
| 1617 | |

DATE MAILED: 05/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/614,790 | Applicant(s) KLEYNE, SHARON F. | |
|---|---|---|---|
| | Examiner Michael A. Willis | Art Unit 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *75-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Applicant's response of 8 February 2002 is entered. Claims 44-74 are cancelled. New claims 75-82 are added. Any previous rejections that are not restated in this Office Action are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 75-82 are pending.

### *Response to Amendment*

Claims 75-82 are rejected under 35 USC 103(a) as being unpatentable over Embleton et al (WO 97/23177) in view of Laibovitz et al (US Pat. 5,997,518) for reasons as stated in previous Office Actions.

Applicant argues that Embleton does not disclose administration of less than 3 microliters of fluid and asserts that Embleton is limited to the range of 3-8 microliters. Applicant's argument is not found convincing in that Embleton teaches amounts of less than 20 microliters, with a preferred volume of less than 10 microliters, and the most preferred range of 3-8 microliters (see page 3, lines 34-37). While the range of 1-3 microliters as claimed is outside the most preferred range of 3-8 microliters of Embleton, the disclosure of "less than 10 microliters" does in fact encompass 1-3 microliters. Furthermore, it is noted that Laibovitz specifically discloses delivery of volumes of 1.3-2.9 microliters (see col. 13, lines 25-30).

Applicant further argues that Embleton does not disclose treatment with an aqueous fluid that consists essentially of water. In support of the argument,

applicant submits two Declarations that assert that (1) artificial tear/dry eye therapies, comfort drops, or irrigation fluids necessarily contain ingredients other than water, and (2) the use of irrigation fluids requires more than 3 microliters to be effective. The Declaration regarding the ineffectiveness of less than 3 microliters as an irrigation fluid is found convincing. However, the Declaration asserting that artificial tears, dry eye therapies, and comfort drops as taught by Embleton necessarily include other ingredients which are essential for their beneficial effects is not found convincing. It is the position of the examiner that water is an art-recognized dry eye therapy or that one of ordinary skill in the art would understand that the phrase "artificial tears" includes water. As evidence that artificial tears include water, Examiner notes that US Pat. 5,627,611 (Scheiner) entitled "Artificial Tears" clearly discloses the use of water (see abstract, lines 1-6). The invention "introduces artificial tear fluid to relieve...chronic dry-eye condition" (see col. 1, lines 9-11). Additionally, US Pat. 5,307,095 (Ogura) entitled "Eye-Moistening Device" clearly discloses the use of water in an eye-moistening device (see abstract, lines 4-9). Ogura discloses that water in the form of atmospheric humidity is used to treat dry eyes (see col. 1, lines 27-31). Therefore, since water is an art-recognized artificial tear/dry eye therapy, Embleton's teaching of water for an artificial tear/dry eye therapy would be understood by one of ordinary skill in the art to include fluids consisting essentially of water.

Applicant further argues that Embleton does not teach average drop size of less than 20 microns, and that Embleton does not teach a mist. However, it is

noted that Laibovitz specifically teaches drops in the range of 1-5 microns, and specifically uses the term mist, thus providing the remedy for any deficiencies of Embleton. Furthermore, in response to applicant's request for evidence that a mist and a jet or stream of droplets are not different, the Examiner respectfully makes reference to the Webster's II: New Riverside University Dictionary (1984) which includes the definition of a mist as fine drops of a liquid, such as a perfume, sprayed into the air. This is entirely consistent with Embleton's use of the phrase "jet or stream of droplets" for application to the eye. It is clear that there is no distinction between a mist and a "jet or stream of droplets" as used by Embleton.

Applicant argues that the apparatus of Laibovitz is not disclosed as suitable for moisturizing the eye. The examiner agrees, and notes that Laibovitz is combined with Embleton for a rejection under 35 USC 103 rather than cited as a 35 USC 102 reference. In response to applicant's argument that Laibovitz does not fill in the gaps in the teaching of Embleton, it is noted that Laibovitz specifically teaches administering 1-25 microliters of fluid in 1-5 micron-sized drops in the form of a mist, which appears to perfectly and completely fill in any gaps in the teachings of Embleton. In response to applicant's assertion that it is improper to combine Laibovitz with Embleton, the motivation for the combination comes from the fact that Embleton teaches the desirability of applying small volumes of liquid in ophthalmic treatment, while Laibovitz teaches an apparatus for the delivery of small volumes of liquid to the eye. Therefore, the combination of references is proper.

***Conclusion***

The prior art made of record in this Office Action is not relied on for new grounds of rejection of the claims, but rather is used to define terms of the art in order to address applicant's arguments. Therefore, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is

assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Michael A. Willis
Examiner
Art Unit 1617

April 26, 2002

MICHAEL G. HARTLEY
PRIMARY EXAMINER